

WE CLAIM:

- 1 1. A storage stable fosinopril tablet comprising fosinopril and a combination of
2 colloidal silicon dioxide and talc.
- 1 2. The storage stable tablet of claim 1, wherein the fosinopril comprises one or more of
2 free fosinopril acid and pharmaceutically acceptable salts of fosinopril.
- 1 3. The storage stable tablet of claim 2, wherein the pharmaceutically acceptable salt of
2 fosinopril comprises one or more of fosinopril sodium, fosinopril magnesium and
3 fosinopril calcium.
- 1 4. The storage stable tablet of claim 3, wherein the pharmaceutically acceptable salt
2 comprises fosinopril sodium.
- 1 5. The storage stable tablet of claim 1, wherein the colloidal silicon dioxide comprises
2 from about 0.25% to about 10% by weight of the total tablet weight.
- 1 6. The storage stable tablet of claim 1, wherein the talc comprises from about 0.25% to
2 about 5% by weight of the total tablet weight.
- 1 7. The storage stable tablet of claim 1, wherein the tablet further comprises one or more
2 pharmaceutically acceptable excipients.
- 1 8. The storage stable tablet of claim 7, wherein the one or more pharmaceutically
2 acceptable excipients comprise one or more of diluent, disintegrant, binder, coloring
3 agent, and flavoring agent.
- 1 9. The storage stable tablet of claim 8, wherein the diluent comprises one or more of
2 calcium carbonate, calcium phosphate-dibasic, calcium phosphate-tribasic, calcium
3 sulfate, cellulose-microcrystalline, cellulose powdered, dextrates, dextrans, dextrose
4 excipients, fructose, kaolin, lactitol, lactose, mannitol, sorbitol, starch, starch
5 pregelatinized, sucrose, sugar compressible and sugar confectioners.
- 1 10. The storage stable tablet of claim 9, wherein the diluent comprises lactose.
- 1 11. The storage stable tablet of claim 8, wherein the binder comprises one or more of
2 methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose,

- 3 polyvinylpyrrolidone, gelatin, gum arabic, ethyl cellulose, polyvinyl alcohol,
4 pullulan, pregelatinized starch, agar, tragacanth, alginic acid derivatives and
5 propylene glycol, and alginate.
- 1 12. The storage stable tablet of claim 11, wherein the binder comprises
2 polyvinylpyrrolidone.
- 1 13. The storage stable tablet of claim 8, wherein the disintegrant comprises one or more
2 of low substituted hydroxypropyl cellulose, carboxymethyl cellulose, calcium
3 carboxymethyl cellulose, sodium carboxymethyl cellulose, croscarmellose sodium,
4 starch, crystalline cellulose, hydroxypropyl starch, and partly pregelatinized starch.
- 1 14. The storage stable tablet of claim 13, wherein the disintegrant comprises
2 croscarmellose sodium.
- 1 15. The storage stable tablet of claim 1, wherein the tablet further comprises one or more
2 additional active ingredients.
- 1 16. The storage stable tablet of claim 15, wherein the one or more additional active
2 ingredients comprise a diuretic comprising one or more of chlorthalidone,
3 furosemide, triameterene, amiloride, spironolactone, and thiazide diuretics.
- 1 17. The storage stable tablet of claim 16, wherein the thiazide diuretic comprises one or
2 more of chlorothiazide, hydrochlorothiazide, flumethiazide and
3 bendroflumethiazide.
- 1 18. The storage stable tablet of claim 17 wherein the thiazide diuretic comprises
2 hydrochlorothiazide.
- 1 19. The storage stable tablet of claim 15, wherein the one or more additional active
2 ingredients comprise one or more of antidepressants, antidiabetics, antiulcers,
3 analgesics, antihypertensives, antibiotics, antipsychotics, antineoplastics,
4 antimuscarinics, diuretics, antimigraine agents, antivirals, anti-inflammatory agents,
5 sedatives, antihistaminics, antiparasitic agents, antiepileptics and lipid lowering
6 agents.

- 1 20. The storage stable tablet of claim 15, wherein the one or more additional active
2 ingredients comprise one or more of enalapril, captopril, benazepril, lisinopril,
3 ranitidine, famotidine, ranitidine bismuth citrate, diltiazem, propranolol, verapamil,
4 nifedipine, acyclovir, ciprofloxacin, simvastatin, atorvastatin, lovastatin, divalproex,
5 venlafaxine, citalopram, paroxetine, selegiline, midazolam, fluoxetine, acarbose,
6 buspirone, nimesulide, captopril, nabumetone, glimepiride, glipizide, etodolac,
7 nefazodone and their pharmaceutically acceptable salts.
- 1 21. The storage stable tablet of claim 1, wherein greater than approximately 98% of an
2 initial amount of fosinopril sodium remains after storage for three months at 40°C
3 and 75% relative humidity as measured by high performance liquid chromatography.
- 1 22. The storage stable tablet of claim 1, wherein greater than approximately 98% of an
2 initial amount of fosinopril sodium remains after storage for one week at 60°C as
3 measured by high performance liquid chromatography.
- 1 23. The storage stable tablet of claim 22, wherein greater than approximately 99% of an
2 initial amount of fosinopril sodium remains after storage for one week at 60°C as
3 measured by high performance liquid chromatography.
- 1 24. The storage stable tablet of claim 1, wherein greater than approximately 98% of an
2 initial amount of fosinopril sodium remains after storage for one week at 60°C as
3 measured by high performance liquid chromatography.
- 1 25. The storage stable table of claim 7, wherein the tablet comprises approximately 20%
2 by weight of fosinopril sodium, approximately 45% by weight of anhydrous lactose,
3 approximately 20% by weight of microcrystalline cellulose, approximately 3.5% by
4 weight of crospovidone, approximately 5% by weight of polyvinylpyrrolidone,
5 approximately 2.5% by weight of colloidal silicon dioxide, and approximately 4.0%
6 by weight of talc.
- 1 26. A storage stable fosinopril tablet comprising:
2 from about 1% to about 40% by weight fosinopril sodium;
3 up to 25% by weight of a diuretic;

- 4 from about 20% to about 85% by weight of diluent;
5 from about 1% to about 10% by weight of disintegrant;
6 from about 1% to about 10% by weight of binder;
7 from about 0.25% to about 10% by weight of colloidal silicon dioxide; and
8 from about 0.25% to about 5% by weight of talc,
9 wherein the weights are percentages of the total tablet weight.
- 1 27. A process for preparing storage stable fosinopril tablets, the process comprising the
2 steps of:
3 a. blending fosinopril in one or more of its free acid form and its
4 pharmaceutically acceptable salts with one or more pharmaceutically
5 acceptable excipients to form a blend,
6 b. optionally granulating the blend to form granules;
7 c. lubricating the blend or granules with colloidal silicon dioxide and talc; and
8 d. compressing into tablets.
- 1 28. The process according to claim 27, further comprising granulating the blend of step
2 (a).
- 1 29. The process according to claim 28, wherein granulating the blend of step (a)
2 comprises a wet granulation process.
- 1 30. The process according to claim 28, wherein granulating the blend of step (a)
2 comprises a dry granulation process.
- 1 31. The process according to claim 27, wherein the blend of step (a) further comprises
2 one or more additional active ingredients.
- 1 32. The process according to claim 31, wherein the additional active ingredient
2 comprises one or more of a diuretic comprising chlorthalidone, furosemide,
3 triameterene, amiloride, spironolactone, and thiazide diuretics.
- 1 33. The process according to claim 32, wherein the thiazide diuretic comprises one or
2 more of chlorothiazide, hydrochlorothiazide, flumethiazide and
3 bendroflumethiazide.
- 1 34. The process according to claim 33, wherein the thiazide diuretic comprises

- 2 hydrochlorothiazide.
- 1 35. The process according to claim 27, further comprising using high performance liquid
2 chromatography to measure the amount of fosinopril after storage.
- 1 36. The process according to claim 35, wherein greater than approximately 98% of an
2 initial amount of fosinopril remains after storage for three months at 40°C and 75%,
3 the amount of fosinopril being measured by high performance liquid
4 chromatography.
- 1 37. The process according to claim 35, wherein greater than approximately 99% of an
2 initial amount of fosinopril remains after storage for one week at 60°C, the amount
3 of fosinopril being measured by high performance liquid chromatography.
- 1 38. A method for one or more of treating hypertension in a mammal and the
2 management of heart failure as an adjunctive therapy in a mammal, the method
3 comprising administering to the mammal one or more fosinopril tablets comprising
4 fosinopril in one or more of its free acid form and its pharmaceutically acceptable
5 salts, colloidal silicon dioxide, and talc.
- 1 39. The method according to claim 38, wherein the tablet further comprises a second
2 active ingredient.
- 1 40. The method according to claim 39, wherein the second active ingredient comprises a
2 diuretic comprising one or more of chlorthalidone, furosemide, triameterene,
3 amiloride, spironolactone, and thiazide diuretics.
- 1 41. The method according to claim 40, wherein the thiazide diuretic comprises one or
2 more of chlorothiazide, hydrochlorothiazide, flumethiazide and
3 bendroflumethiazide.
- 1 42. The method according to claim 41, wherein the thiazide diuretic comprises
2 hydrochlorothiazide.
- 1 43. The method according to claim 38, wherein greater than approximately 98% of an
2 initial amount of fosinopril remains after storage for three months at 40°C and 75%
3 relative humidity as measured by high performance liquid chromatography.

- 1 44. The storage stable tablet of claim 38, wherein greater than approximately 99% of an
2 initial amount of fosinopril sodium remains after storage for one week at 60°C as
3 measured by high performance liquid chromatography.